

REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 16-35 are pending in the present application. Support for new claims 16-35 may be found generally throughout the specification and in original claims 1-7. Claims 1-15 have been canceled. Any unclaimed subject matter may be the subject of one or more divisional applications.

The Information Disclosure Statement filed on April 8, 2002 was objected to for not being in compliance with the provisions of 37 CFR 1.97, 1.98 and MPEP §609. In particular, the Official Action states that the JP 00279312 reference was not considered because a copy was not present in the application.

However, there was a JP 6279312 publication that was filed with the Information Disclosure Statement (IDS). As evidence, applicants enclose with this amendment a copy of the postcard receipt indicating that eight references were filed with the IDS. As only seven references were considered and present in the application, it is respectfully submitted that the JP 06279312 publication was perhaps misplaced during the handling of the application. Accordingly, it is respectfully submitted that the JP 06279312 publication be considered at this time. For the convenience of the Patent Office, applicants submit with the

present amendment a copy of the JP 6279312 publication and a PTO-1449 Form citing the JP 6279312 publication.

Claims 1-7 were objected to for containing several informalities.

However, as noted above, claims 1-7 have been canceled. It is believed that new claims 16-35 have been drafted so as to avoid the informalities identified by the Official Action.

Claims 1-7 were rejected under 35 USC §112, second paragraph, for allegedly being indefinite. This rejection is respectfully traversed.

In imposing the rejection, the Official Action alleged that claim 1 was an incomplete method claim. The independent claims that are now pending in the application are claims 16, 25 and 33. Applicants believe that each of the independent claims is a "complete" claim. Each of the independent claims indicates that the starting material is a milk product. The steps of the method are clearly stated and each claim indicates that fractions of IGF-1 and TGF- β are obtained.

The Official Action also objects to the phrase "increasing salt concentration or pH". However, pH and salt concentrations are recited in each independent claim for the first and second eluents. Support for these recitations may be found in the present specification at page 6, lines 19-24. It is believed to be apparent the same ranges apply to the sodium chloride and potassium chloride eluents in that the fractions are

identified in that passage in the specification as "typically" eluted under the recited conditions. This is further supported by Example 4, which teaches the subsequent treating of a hydroxyapatite column with eluents containing 0.12 M NaCl/25 mM phosphate and 0.35 M NaCl/25 mM phosphate to obtain separate fractions of IGF-1 and TGF- β .

While the recitation "increased salt content or pH" appears in some of the dependent claims, it is believed that one of ordinary skill in the art would understand the recitation in view of the changes that have been made to the independent claims.

As to the third eluent recited in the dependent claims, the third eluent is a salt solution with a pH of 5.5-8. The concentration is typically 0.3-0.5 M. Support for this recitation may be found in the present specification at page 6, lines 29-32.

Applicants believe that each of the independent claims has been drafted to clearly recite the ratio of IGF-1 to TGF- β for each fraction.

Claim 5 was objected to for reciting the phrase "high surface velocity" and "high liquid load". However, the claims have been drafted so these phrases are no longer recited. Rather, claims 28 and 33 recite the surface velocity and liquid load parameters.

Thus, in view of the above, applicants believe that the new claims have been drafted in a manner so as to avoid the rejection imposed on claims 1-7.

As to the step recovering of a basic fraction from the milk product, applicants believe that the step would have been definite to one skilled in the art. The step indicates that the basic fraction is obtained from a milk product by means of cationic exchange chromatography. Thus, it is indicated how the fraction is obtained.

Furthermore, it is described in the present specification at page 4, line 31 to page 5, line 4 that the cationic exchange resin used in step a) can be of any suitable type known in the field. Additionally, the specification goes on to teach the preferred particle size of the cationic exchange resin and preferred steps for packing and loading the column. In this regard, the specification even refers to United States Patent No. 5,596,082 which discusses how the starting material is initially loaded onto the column.

Thus, it is believed that the step of recovering a basic fraction from the milk product as recited in claim 17 is definite to one skilled in the art. Furthermore, it is noted that independent claims 25 and 33 further recite how to obtain the basic fraction. Thus, it is believed that the rejection does not extend to claims 25 and 33 or any of their corresponding dependent claims.

In view of the above, applicants believe that claims 16-35 are definite to one skilled in the art.

Claims 1-7 were rejected under 35 USC §112, first paragraph, for allegedly not satisfying the enablement requirement. Applicants believe the present amendment overcomes this rejection.

In imposing the rejection, the Official Action alleges that the present disclosure is not enabling for a step of eluting a basic fraction from a cationic exchange column by utilizing any elution buffer.

The Examiner is respectfully reminded that it is a well founded principle that any assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubt so expressed.

As a matter of law, the expressed teaching of the patent specification cannot be controverted by mere speculation and unsupported assertions on the part of the Patent Office. As stated by the Court of Customs and Patent Appeals in the case of *In re Dinh-Nguyen and Stanhagen*, 181 USPQ 46 (CCPA 1974):

Any assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubt so expressed. 181 USPQ at 47.

Such a standard must be applied with great care when the Examiner's conjecture is contrary to the teachings of the specification.

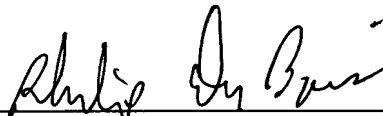
While the Official Action cites to several publications that utilize elution steps under particular conditions, none of the publications suggest that practicing step a) would be an unpredictable endeavor or constitute an undue burden in view of the present disclosure. Indeed, as noted above, the specification plainly teaches one skilled in the art how to obtain the basic fraction.

Thus, in view of the above, applicants respectfully request that the rejection be withdrawn.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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APPENDIX:

The Appendix includes the following items:

- copy of XP-002139233 (JP 6279312), abstract
- copy of postcard receipt stamped April 8, 2002,
evidencing filing of IDS and eight cited references
- PTO Form 1449 citing JP 6279312